

## REMARKS

The pending Office Action addresses claims 1, 3-44, 46-54, and 86-93. Claims 25, 29, 32, 39-44, 47, and 49-54 are withdrawn. Remaining claims 1, 3-7, 11-23, 26-28, 30, 31, 33-38, 45, 46, 48, and 86-93 stand rejected, and claims 8-10, 24, 34, and 35 are objected to.

### *Amendments to the Claims*

Claim 26 is amended to recite that at least one of the first and second guide members includes a first pathway formed therein and adapted to align with a first bore formed in a spinal fixation plate, and a second pathway formed therein and adapted to align with a second bore formed in the spinal fixation plate. Support for this amendment can be found in claim 30, which is now canceled, and throughout the specification and drawings. Claim 31 is amended to depend from and correspond to amended claim 26. Claim 46 is amended to depend from 26. Claims 86 and 91 are amended to include that first and second guide members are slidably movable with respect to one another. Support for these amendments can be found in claim 1, and throughout the specification and the drawings. No new matter is added

### *Claim Objections*

Claim 46 is objected to because it depends from a cancelled claim. Claim 46 is amended to depend from claim 26, as noted above, to overcome this objection.

### *Rejections Pursuant to 35 U.S.C. §102*

(1) *U.S. Patent No. 4,773,402 of Asher et al.*

Claims 1, 14, 26, and 27 are rejected pursuant to 35 U.S.C. §102(b) as being anticipated by U.S. Patent No. 4,773,402 of Asher et al. The Examiner argues that Asher discloses a guide device substantially as claimed. Applicants respectfully disagree.

Independent claim 1 is directed to a guide device for use with a spinal implant. The guide device includes an elongate support member and first and second arms each having a proximal end coupled to the elongate support member and a distal end. At least one of the first and second arms is

slidably movable along the support member to allow a distance between the first and second arms to be adjusted, and at least one of the first and second arms includes a guide member coupled to a distal end thereof and having at least one pathway formed therein for receiving a tool. The guide member is adapted to be juxtapositioned on a spinal implant such that the at least one pathway in the guide member is aligned with a corresponding bore formed in the implant.

Asher does not teach or suggest a guide device having an arm that is slidably movable along a support member to allow a distance between first and second arms to be adjusted. Asher is directed to a transacral *implant* for supporting the spine. The implant includes a base plate (27) and first and second rods (28, 29) that are coupled to the base plate (27) and that are positioned along and secured to adjacent vertebrae to correct a spinal deformity. The implant includes bridging elements (54) that extend between the rods (28, 29) for *maintaining the spatial relationship* between the rods (28, 29). There is no component described in Asher that allows the distance between the rods (28, 29) to be adjusted, as required by claim 1. In fact, the inclusion of the bridging element (54) in the implant of Asher does just the opposite – it maintains the distance between the two rods (28, 29).

Asher also fails to teach a guide member coupled to a *distal end* of at least one of a first and second arm. The Examiner argues that arcuate sections (60, 61) of a yoke and foot element (59) are guide members as recited by claim 1. The yoke and foot element (59), however, extends between the rods (28, 29) at a location proximal to a distal end of each rod (28, 29). Thus, the yoke and foot element (59) does not couple to a distal end of the rods (28, 29), as required by claim 1.

Asher also does not teach a guide member that is adapted to be juxtapositioned on a spinal implant such that at least one pathway in the guide member is aligned with a corresponding bore formed in the implant. As shown in FIG. 1, the distal ends of the rods (28, 29) are attached to a base plate (27). The base plate (27) would thus prevent the yoke and foot element (59), which extends between the rods (28, 29) at a location proximal to the base plate (27), to be juxtaposed on a spinal implant.

Accordingly, independent claim 1, as well as claim 14, which depends therefrom, therefore distinguishes over Asher.

Independent claim 26 is directed to an adjustable guide member for use with a spinal fixation plate. The adjustable guide member includes a first member having an elongate support and a first arm mated to one end thereof. The first arm extends in a direction transverse to the support and includes a first guide member mated to a distal end thereof. A second member has a second arm with a first end adapted to slidably mate with and extend in a direction transverse to the elongate support of the first member. The second arm has a second guide member mated to a distal end thereof. The adjustable guide member further includes an adjustment mechanism formed on the second member and effective to allow slidable movement of the second member along the elongate support of the first member. At least one of the first and second guide members includes a first pathway formed therein and adapted to align with a first bore formed in a spinal fixation plate, and a second pathway formed therein and adapted to align with a second bore formed in the spinal fixation plate.

Asher does not teach or suggest a first guide member mated to a distal end of a first arm and a second guide member mated to a distal end of a second arm, as required by claim 26. The Examiner argues that the arcuate sections (60, 61) of the yoke and foot element (59) of Asher are guide members as recited by claim 26. However, the arcuate sections (60, 61) are formed as a single component, both being part of the yoke and foot element (59). Thus, the device disclosed in Asher does not include *both* a first guide member and a second guide member.

Asher also does not teach that at least one of the first and second guide members has a first pathway adapted to align with a first bore formed in a spinal fixation plate, and a second pathway adapted to align with a second bore formed in the spinal fixation plate. Each arcuate section (60, 61) includes only a single pathway extending therethrough, and this pathway is used to mate the arcuate sections (60, 61) to the rods (28, 29). The arcuate sections (60, 61) do not include any additional pathways that could be aligned with a first bore and a second bore formed in a spinal plate.

Claim 26, as well as claim 27 which depends therefrom, therefore distinguishes over Asher.

(2) *U.S. Patent No. 4,733,657 of Kluger*

Claims 26, 28, 30, 31, and 33 are rejected pursuant to 35 U.S.C. §102(b) as being anticipated by

U.S. Patent No. 4,733,657 of Kluger. The Examiner argues that Kluger discloses a guide device substantially as claimed. Applicants respectfully disagree.

Claim 26 recites that one of the first and second guide members includes a first pathway formed therein and adapted to align with a first bore formed in a spinal fixation plate, and a second pathway formed therein and adapted to align with a second bore formed in the spinal fixation plate. Kluger does not teach a guide member with first and second pathways that can align with first and second bores in a plate, as required by claim 26. Kluger discloses a device for aligning a spinal column that includes two arms (5, 11) coupled to a shaft (4) at a first end. The second end of each arm (5, 11) includes a support surface (8) and a resting surface (13), each of which include a hole formed therethrough. The Examiner argues that the holes in the support and resting surfaces (8, 13) formed first and second pathways. The holes, however, are axially aligned with one another and thus form one continuous opening through the surfaces (8, 13). As a result, one of the holes cannot be aligned with a first bore in a plate while the second hole is aligned with a second bore in the plate, as required by claim 26. Alignment of the pathways with two separate bores cannot be achieved with the device disclosed in Kluger. Accordingly, independent claim 26, as well as claims 28, 30, 31, and 33, which depends therefrom, therefore distinguishes over Kluger.

(3) *U.S. Patent No. 5,423,826 of Coates et al.*

Claims 1, 3-7, 11-13, 15-23, 26, 28, 30, 31, 36-38, 48, and 86-93 are rejected pursuant to 35 U.S.C. §102(b) as being anticipated by U.S. Patent No. 5,423,826 of Coates et al. The Examiner continues to argue that Coates discloses a guide device substantially as claimed. Applicants respectfully disagree.

Claim 1 recites that at least one of the first and second arms is slidably movable along a support member to allow a distance between the first and second arms to be adjusted. Coates does not teach or suggest a guide device having an arm that is *slidably* movable along a support member. Coates teaches a drill guide having two arms (151, 152) that are pivotally coupled to one another, as shown in FIGS. 17 and 19. A threaded locking rod (155) extends through and threadably mates to the arms (151, 152) such that *rotation* of the locking rod (155) pivots the arms. Neither arm (151, 152) slides along the locking

rod (155).

In the response to Applicant's previous arguments, the Examiner states that:

Applicant also argues that the arms of Coates do not slide along an elongate support, however, this is not persuasive because clearly the elongate support member moves along the arms even as Applicant admits on page 12 of the amendment. Any surgeon can make "smooth adjustments" with the knob of Coates device to permit a "smooth movement" of the arms along the elongate member.

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Applicants agree with the Examiner that the two arms *move* along the support member, but Applicants point out that the claim requires that arms to be *slidably* movable. Coates does not teach or suggest that the arms (151, 152) slide along the locking rod (155). While the Examiner seems to suggest that "smooth movement" of the arms (151, 152) is equivalent to "slidable movement" as required by claim 1, this is not the case. Slidable movement involves moving along a surface, such as the arm moving along the support member. Smooth movement of the arms (151, 152) caused by the rotation of the locking rod (155) as described by Coates is not equivalent to the arms (151, 152) sliding, or moving along, the locking rod (155). The rotation of the locking rod (155) merely caused the arms (151, 152) to move farther apart or closer together, and not to slide along the locking rod (155). Accordingly, independent claim 1, as well as claims 3-7, 11-13, and 15-23, which depend therefrom, therefore distinguishes over Coates.

Independent claim 26, like claim 1, requires a guide member having a second arm with a first end adapted to slidably mate with and extend in a direction transverse to an elongate support. As stated above with regard to claim 1, Coates does not teach or suggest an arm that is *slidably* mated to an elongate support. Thus, claim 26 likewise distinguishes over Coates.

Independent claims 86 and 91, likewise, require first and second arms *slidably* movable with respect to one another. As stated above, Coates does not teach or suggest an arms that are slidably movable. Thus, claims 86 and 91, as well as claims 87-90, 92, and 93 which depend therefrom,

distinguishes over Coates.

***Conclusion***

Applicants submit that all pending claims are now in condition for allowance, and allowance thereof is respectfully requested. The Examiner is encouraged to telephone the undersigned attorney for Applicants if such communication is deemed to expedite prosecution of this application.

Respectfully submitted,

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